Docket No.: 61959(51580)
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Yow-Pin Lim, *et al.*

Application No.: 10/578,449 | Confirmation No.: 2106

Filed: April 4, 2007 | Art Unit: 1654

For: *PREPARATION AND COMPOSITION OF INTER-ALPHA INHIBITOR PROTEINS FROM HUMAN PLASMA FOR THERAPEUTIC USE* | Examiner: A. A. Mohamed

RESPONSE TO RESTRICTION REQUIREMENT

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir/Madam:

Applicants submit this paper in response to the Office Action dated June 19, 2009, along with a Petition for a one-month extension of time and the required fee based on small entity status, in the above-referenced patent application. Applicants believe that no additional fees are required for entry and consideration of this paper. Nevertheless, Applicants authorize the Director to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to Deposit Account No. 04-1105, under Order No. 61959(51580).

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Claims 1, 2, 10, 12-15, 21, 25, 27, 28, 31, 40-42, 45-48, 56, 57, 77-86, 88, 96, 98, 99, and 101 are pending in the application and are subject to restriction. The Office Action, on page 2, requires restriction to one of the following groups under 35 U.S.C. §121 and 35 U.S.C. §372:

Group I – Claims 1, 2, 10, 12-15, 21, 25, 27, 28, 31, 40-42, 45-48, 56, 57, 77-86, and 101, drawn to a process for producing a blood plasma-derived I-alpha-Ip (IαIp) and P-alpha-I (PαI) composition comprising a mixture of inter-alpha inhibitor protein (IαI) and pre-alpha protein (PαI), pharmaceutical and kit formulation thereof and to a method of treating an inflammation related disorder, cancer and infectious disease in a subject.

Group II – Claim 88, drawn to a method of treating a subject for acute inflammatory disease by determining the pre-treatment level of inter-alpha inhibitor protein and administering an effective amount of I-alpha-Ip to treat the subject.

Group III – Claim 96, drawn to a method for predicting a response to an I-alpha-Ip therapy by assaying a sample of inter-alpha inhibitor proteins.

Group IV – Claim 98, drawn to a method for monitoring the progress of a subject being treated with an I-alpha-Ip therapy by determining the pre-treatment level of inter-alpha inhibitor proteins and administering an effective amount of I-alpha-IP.

Super Group V – Claim 99, drawn to a kit for therapy having 8! = 40,320 possible kits.

In response to the restriction requirement, Applicants hereby provisionally elect with traverse the invention of Group I, corresponding to claims 1, 2, 10, 12-15, 21, 25, 27, 28, 31, 40-42, 45-48, 56, 57, 77-86, and 101 for continued examination. Applicants respectfully traverse the requirements for restriction and election.

In accordance with PCT Rule 13.1, claims lack unity of invention if they are not so linked to form a single general inventive concept. Pursuant to PCT Rule 13.2, this can be shown if the claims lack the same or corresponding special technical feature(s). In order to establish that the claims lack the same or corresponding special technical feature(s), the Examiner must cite a piece of prior art that shows that the same or corresponding special technical feature was known in the art. In the Office Action, there is no citation of any prior

art that establishes that the same or corresponding special technical feature was known in the art. For this reason, the restriction requirement is improper and must be withdrawn.

Moreover, Applicants assert that the subject matter of these groups represent different embodiments of a single inventive concept for which a single patent should issue. The pending claims represent an intricate web of knowledge, continuity of effort, and consequences of a single invention, which merit examination of all of these claims in a single application.

More particularly, a single, searchable, unifying aspect links all of the claims. This single, searchable, unifying aspect comprises use of a blood plasma-derived Iαlp composition. In other words, the use of a blood plasma-derived Iαlp is the same or corresponding special technical feature common to all the claims.

Second, Applicants submit that a sufficient search and examination with respect to the subject matter of all claims can be made without serious burden. As M.P.E.P. § 803 states:

> If the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to independent or distinct inventions.

That is, even if the above-enumerated groups of claims are drawn to distinct inventions, the Examiner must still examine the entire application on the merits because doing so will not result in a serious burden. This is especially true given that: the five groups of claims are all directed to methods of using a blood plasma-derived Iαlp composition; the robust and extensive computerized search engines and databases at the Examiner's disposal; and the fact that in searching the use of a blood plasma-derived Iαlp, the Examiner will necessarily have searched all the various aspects recited in the pending claims.

Accordingly, in the interest of cost and time savings to both Applicants and the United States Patent and Trademark Office, Applicants respectfully request that the restriction requirement be reconsidered and the elected claims of Group I be rejoined with those of Groups II, III, IV, and V, so that claims all pending claims may be presently examined.

If a telephone call to Applicants' representatives would be helpful in resolving any issues in connection with this response or would otherwise expedite prosecution of the application, Applicants invite the Examiner to contact the undersigned at the telephone number listed below.

Dated: August 19, 2009

Respectfully submitted,

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